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510(k) SUMMARY

This Summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K073612

A. Introduction:

According to the requirements of 21 CFR 807.92 the following information provides sufficent detail to understand the basis for a determination of substantial equivalence.

B. Submitter's information

Name:	Thermo Fisher Scientific Oy
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Contact person:	Päivi Sormunen, Vice President of QRC
Date of Preparation:	December 10th, 2007

C. Device name

Proprietary name:	Uric Acid (AOX), codes 981391 and 981788
Common name:	Uric acid
Classification:	Clinical Chemistry
Class:	I
Product Code:	KNK
Proprietary name:	sCal, code 981831
Common Name:	Calibrator, Multi-Analyte Mixture
Classification:	Clinical Chemistry
Class:	II
Product Code:	JIX
Proprietary name:	Nortrol, code 981043
Common Name:	Multi-analyte Controls (Assayed and unassayed)
Classification:	Clinical Chemistry
Class:	I
Product Code:	JJY
Proprietary name:	Abtrol, code 981044
Common Name:	Multi-analyte Controls (Assayed and unassayed)
Classification:	Clinical Chemistry
Class:	I
Product Code:	JJY

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D. Intended Use

Uric Acid (AOX)
For *in vitro* diagnostic use in the quantitative determination of uric acid concentration in human serum or plasma on T60 instrument.

sCal, code 981831
For *in vitro* diagnostic use on T60 instrument. sCal is used as a multicalibrator for quantitative measurements using methods defined by Thermo Fisher Scientific Oy.

Nortrol
For *in vitro* diagnostic use for quantitative testing on T60 instrument. Nortrol is a control serum to monitor trueness and precision of the analytes listed in the separate Nortrol value sheet. The given values are valid for T60 Clinical Chemistry Instruments using methods defined by Thermo Fisher Scientific Oy.

Abtrol
For *in vitro* diagnostic use for quantitative testing on T60 instrument. Abtrol is a control serum to monitor trueness and precision of the analytes listed in the separate Abtrol value sheet. The given values are valid for T60 Clinical Chemistry Instruments using methods defined by Thermo Fisher Scientific Oy.

E. Indications for use

The Uric Acid (AOX) test system is intended for quantitative *in vitro* diagnostic measurement of uric acid concentration in human serum or plasma. Such measurements are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure and gout.

For sCal Calibrator, Nortrol and Abtrol see intended use.

F. Substantial Equivalence

Bayer Corporation, model Bayer ADVIA 2400 Chemistry System.

Bayer Corporation item: Bayer ADVIA Uric Acid (UA) assay.

G. Substantial equivalence -similarities

Uric Acid is substantially equivalent to other devices legally marketed in United States. We claim equivalence to the Bayer ADVIA Uric Acid (UA) assay (K991576).

The following table compares the Uric Acid with the predicate device

Table 1

Attribute	**New device #1**	**Predicate device #1**
Intended Use	For *in vitro* diagnostic use in the quantitative determination of uric acid concentration in human serum or plasma on T60 instrument.	For *in vitro* diagnostic use in the quantitative determination of uric acid in human serum, plasma and urine on the ADVIA® 1650 Chemistry system. Such measurements are used in the diagnosis and treatment of renal failure, gout and eclampsia
Indication for Use	The Uric Acid test system is intended for quantitative *in vitro* diagnostic measurement of uric acid concentration in human serum or plasma. Such measurements are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure and gout.	See intended use.
Assay Protocol	Uric acid is oxidized to allantoin by uricase. The generated hydrogen peroxide reacts with 4-aminoantipyrine (4-AAP) and N-ethyl-N-(hydroxy-3-sulfopropyl)-m-toluidin (TOOS) to a blue violet dye. The absorbance of the formed colour is measured at 540 nm.	The uric acid is converted by uricase to allantoin and hydrogen peroxide. A colored complex is formed from hydrogen peroxide, 4-aminophenazone and TOOS [*N*-ethyl-*N*-(2-hydroxy-sulfopropyl)-3-methylaniline] under the catalytic influence of peroxide. The absorbance of the complex is measured as an endpoint reaction at 545 nm.
Traceability/Standardization	The value of Uric Acid has been assigned by using NIST SRM 909b as a primary reference.	The ADVIA 1650 Uric Acid method is traceable to the CDC candidate reference method, which uses reference materials from the National Institute of Standards and Technology (NIST) via patient sample correlation.
Sample Type	Serum, plasma (Li-heparin)	Serum, plasma (Li-heparin) and urine
Reagent Storage	Reagents in unopened vials are stable at 2…8 °C until the expiration date printed on the label, when protected from light.	Store at 2° – 8°C. Unopened reagents are stable until the expiration date printed on the product label.

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Expected Values	Serum, adult: Male: 3.5 - 7.2 mg/dl (210 - 420 µmol/l) Female: 2.6 - 6.0 mg/dl (150 - 350 µmol/l)	**Serum:** Male: 3.5 – 7.2 mg/dL (208 – 428 µmol/L) Female: 2.6 – 6.0 mg/dL (155 – 357 µmol/L) **Urine** 250 – 750 mg/day (1.48 – 4.43 mmol/day)
Instrument	T60 and DPC T60i, DPC T60i Kusti	ADVIA® 2400 Chemistry system.
Measuring Range	**Serum:** 0.2 - 20.0 mg/dl (10 - 1200 µmol/l)	**Serum:** 0 – 20 mg/dL **Urine:** 0 – 180 mg/dL
Precision	**Within run** Level 1.2 mg/ dL SD= 0.009 CV(%)= 0.8 Level 2.3 mg/ dL SD= 0.017 CV(%)= 0.7 Level 4.4 mg/ dL SD= 0.030 CV(%)= 0.7 Level 8.9 mg/ dL SD= 0.045 CV(%)= 0.5 **Between run** Level 1.2 mg/ dL SD= 0.015 CV(%)= 1.3 Level 2.3 mg/ dL SD= 0.020 CV(%)= 0.9 Level 4.4 mg/ dL SD= 0.030 CV(%)= 0.7 Level 8.9 mg/ dL SD= 0.039 CV(%)= 0.4	**Serum:** **Within run** Level 3.9 mg/dL SD= 0.04 CV(%)= 1.1 Level 8.6 mg/dL SD= 0.10 CV(%)= 1.1 Level 10.0 mg/dL SD= 0.06 CV(%)= 0.6 **Total** Level 3.9 mg/dL SD= 0.07 CV(%)= 1.9 Level 8.6 mg/dL SD= 0.14 CV(%)= 1.6 Level 10.0 mg/dL SD= 0.23 CV(%)= 2.3 **Urine:** **Within run** Level 12.4 mg/dL SD= 0.14 CV(%)= 1.1 Level 23.9 mg/dL SD= 0.16 CV(%)= 0.7

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	Total Level 1.2 mg/ dL SD= 0.026 CV(%)= 2.3 Level 2.3 mg/ dL SD= 0.038 CV(%)= 1.7 Level 4.4 mg/ dL SD= 0.123 CV(%)= 2.8 Level 8.9 mg/ dL SD= 0.094 CV(%)= 1.1	**Total** Level 12.4 mg/dL SD= 0.14 CV(%)=1.1 Level 23.9 mg/dL SD= 1.24 CV(%)= 5.2
Method Comparison	Comparison to Bayer ADVIA 2400 y = 1.06x – 0.12 R = 0.999 range from 0.3 to 12.6 mg/dL N = 105	**Serum:** Technicon DAX y = 1.51x + 0.48 r = 0.994 N = 154 Range 0.2 – 18.0 mg/dL Reference Method y = 1.01x - 0.05 r = 0.999 N = 49 Range 1.7 –19.5 mg/dL **Urine:** Beckman CX7 y = 1.03x – 0.5 r = 0.989 N = 30 Range 8 – 91 mg/dL
Limitations	**Lipemia:** No interference found up to 900 mg/dl (9 g/l) of Intralipid. **Hemolysate:** No interference found up to 1000 mg/dl (10 g/l) of hemoglobin **Bilirubin conjugated:** No interference found up to 11 mg/dl (200 µmol/l) of conjugated bilirubin **Bilirubin total:** No interference found up to 14 mg/dl (250 µmol/l) of unconjugated bilirubin.	**Hemolysate:** No significant interference found up to 525 mg/dl of hemoglobin. **Bilirubin:** No significant interference found up to 30 mg/dl. **Triglycerides:** The effect of triglycerides has been measured at analyte concentrations 3.4 mg/dL and 8.9 mg/ dL. The observed interference is expressed as an interference index. Please refer to ADVIA 1650 Uric Acid (UA) package insert.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 23 2008

Thermo Fisher Scientific Oy
c/o Ms. Päivi Sormunen, Vice President of Industrial Solutions & QRC
Ratastie 2, P.O. Box 100
Fin-01621 Vantaa
Finland

Re: K073612
Trade Name: sCal, Nortrol, Abtrol, Uric Acid (AOX)
Regulation Number: 21 CFR §862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Codes: JIX, JJY, KNK
Dated: April 2, 2008
Received: April 4, 2008

Dear Ms. Sormunen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K073612

Device Name: Uric Acid (AOX), sCal, Nortrol, Abtrol

The Uric Acid test system is intended for quantitative *in vitro* diagnostic measurement of uric acid concentration in human serum or plasma. Such measurements are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure and gout.

For *in vitro* diagnostic use on T60 instrument. sCal is used as a multicalibrator for quantitative measurements using methods defined by Thermo Fisher Scientific Oy

For *in vitro* diagnostic use for quantitative testing on T60 instrument. Nortrol is a control serum to monitor trueness and precision of the analytes listed in the separate Nortrol value sheet. The given values are valid for T60 Clinical Chemistry Instruments using methods defined by Thermo Fisher Scientific Oy.

For *in vitro* diagnostic use for quantitative testing on T60 instrument. Abtrol is a control serum to monitor trueness and precision of the analytes listed in the separate Abtrol value sheet. The given values are valid for T60 Clinical Chemistry Instruments using methods defined by Thermo Fisher Scientific Oy.

Prescription Use __X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K073612